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**APPARATUS WITH AUTOMATIC RESPIRATION
MONITORING AND DISPLAY**

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APPARATUS WITH AUTOMATIC RESPIRATION MONITORING AND DISPLAY

This application claims priority to United States provisional application S.N.
5 60/139,516 filed June 16, 1999.

BACKGROUND OF THE INVENTION

A. Field of Invention

10 The invention relates to respiratory systems such as Non-Invasive Positive Pressure Ventilation (NIPPV), nasal Continuous Positive Airway Pressure (CPAP) and other similar apparatus, used, for example, in the treatment of Sleep Disordered Breathing (SDB) or Obstructive Sleep Apnea (OSA). More particularly, this invention pertains to a respiratory apparatus which uses an automatic baseline tracking technique to monitor and display a patient's respiration, for example during a CPAP titration session of a sleep investigation.:

15 B. Description of The Prior Art

CPAP, NIPPV and similar types of respiratory apparatus function to supply clean breathable gas (usually air, with or without supplemental oxygen) at a prescribed pressure or pressures, synchronously with a patient's respiration. A suitable CPAP apparatus in which the present invention may be incorporated is, for example, the
20 Sullivan® V made by ResMed Ltd. of North Ryde NSW, Australia.

A respiratory apparatus typically includes a blower, an air filter, a mask or other similar patient interface, an air delivery conduit connecting the blower to the mask, and a microprocessor-based control unit. The blower generally includes a servo-controlled motor and an impeller and is used to provide a flow of pressurized air to the patient. The
25 blower may also include a valve for discharging air. Optionally, the apparatus may include a humidifier which can apply moisture to the air supplied through the air delivery

conduit. The control unit is used to control the functions of the blower, and to monitor clinical functions and other parameters associated with respiration. These parameters may be used for the diagnosis of sleep and respiratory disorders. Respiratory disorders such as apnea, snoring, and partial airflow limitations can be inferred by a clinician from
5 the patient's respiration, the associated breathing pattern and signals from other sensors.

A convenient, established way of monitoring respiration during the diagnosis of a sleep disorder consists of analyzing pressure fluctuations obtained from nasal oxygen cannulae inserted into the patient's nares. This provides an indication of respiration flow. If upper-airway irregularities of a significant number are recorded, a CPAP titration
10 session may be ordered. The goal of a CPAP titration session is to determine what level of CPAP treatment is needed to abolish the bulk of the patient's upper-airway irregularities. Throughout the session the CPAP level (pressure) is manually adjusted to resolve the irregularities. During such a session, respiration may be assessed by interpreting the mask pressure signal, a complex pressure signal consisting of the
15 following components: (a) a CPAP component related to the positive airway pressure induced by the blower and having a very low frequency (in the order of 0-0.1 Hz) and high amplitude (in the order of 2-30 cm H₂O); (b) a respiration component related to the normal respiration of the patient and having a relatively low frequency (of about 0.01 Hz) and low amplitude, generally not exceeding 10 mm of H₂O; and possibly (c) a
20 component associated with snoring and having a high frequency in the range of 30-200 Hz and a low amplitude in the order of mm of H₂O. For diagnostic purposes, it is desirable to generate an output signal indicative of the last two components (b) and (c) to derive the respiration sequence referred to herein as the respiration signal.

Prior art respiration monitoring systems use high-pass filtering to separate the
25 desired components from the complex pressure signal. This technique can be unsatisfactory because: (1) if the high-pass filter excludes low-frequency components of the respiratory signal, it will compromise the integrity of the monitored signal; (2) it is slow to track changes in CPAP component, particularly fluctuations due to leaks which are often known to cause step changes in the pressure signal; and (3) if performed in
30 software, it requires high resolution and extensive signal processing.

Another known technique for deriving and monitoring a respiration signal uses a DC-coupled response amplifier without high-pass filtering of the complex pressure signal. The disadvantage of a DC-coupled technique is that the CPAP component appears as a DC offset which must be subtracted from the complex pressure signal so
5 that the respiration signal does not exceed the dynamic range of the measurement system. During a titration study, each adjustment of the CPAP treatment pressure may demand an adjustment of the DC offset, if the respiration signal is to stay within the dynamic range of the monitoring system. Typically a special manual knob is provided for this purpose which allows an operator to eliminate the DC offset. Hence, using a DC-
10 coupled response amplifier is time-consuming and requires a manual operation of the respiratory apparatus, additional training, and constant attention by an operator.

If the CPAP component generated by the blower is continuously known by the respiration monitoring system, an alternate technique would be to subtract this CPAP component from the complex pressure signal sensed in the mask, theoretically leaving
15 just the respiration signal. This technique is impractical because leaks may occur, causing the pressure in the mask to deviate significantly from the pressure set for the blower and because the blower may not be in constant communication with the sensing device and, therefore, the CPAP component may not always be present.

OBJECTIVES AND SUMMARY OF THE INVENTION

20 In consideration of the above, it is an objective of the present invention to provide a respiratory apparatus in which a respiration signal is generated, the signal being automatically adjusted to lie in a predetermined range.

A further objective is to provide a respiratory apparatus capable of displaying a respiration signal to a clinician by calculating a baseline correction and automatically
25 adjusting the baseline to track long and/or short term variations of the respiration signal.

A further objective is to provide a respiratory apparatus which generates a respiration signal indicative of a patient's respiration without the need for an operator to compensate manually for pressure variations produced by the apparatus.

A key advantage of the invention to a clinician performing a sleep study is that
30 the need for intervention during the operation of the subject respiratory apparatus is

reduced or eliminated. The present invention simplifies respiration monitoring without sacrificing signal integrity.

A further advantage of the subject invention is that it provides a respiratory apparatus which displays a respiration signal as an indication of the upper airway
5 resistance in a patient, the apparatus being reliable and easy to use.

Other objectives and advantages of the invention shall become apparent from the following description.

Briefly, a respiratory apparatus constructed in accordance with this invention includes a blower providing a flow of pressurized air to the patient, a patient interface
10 (such as a mask receiving air from the blower), a control unit for managing the blower, and a display to show a respiration signal generated by the control unit. The control unit includes a pressure transducer for sensing the actual instantaneous pressure within the patient interface and for converting this pressure to an electrical pressure signal, and a summer which subtracts a baseline pressure signal from the pressure signal to generate a
15 respiration signal. The baseline signal can be adjusted automatically or manually. For the automatic adjustment of the baseline signal, long term and short term averages of the respiration signal are calculated. These averages are used to adjust the baseline signal in a manner that insures that the respiration signal remains within the predetermined range. Adjusting the baseline pressure signal compensates for changes in the respiration signal
20 caused by the operation of the blower (i.e., the CPAP component) or other factors, such as the development of a sudden leak.

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BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows the elements of a respiratory apparatus constructed in accordance with this invention;

Fig. 2 shows a block diagram for a control unit for the respiratory apparatus of Fig. 1;

Fig. 3 shows a flow chart illustrating the operation of the respiratory apparatus of Figs. 1 and 2; and

Figs. 4A-4E show time dependent graphs of a respiration signal generated by the control unit of Fig. 2 for various operating conditions.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to Fig. 1, a respiratory apparatus 10 constructed in accordance with this invention includes a blower 12 adapted to provide pressurized air, a flexible conduit 14, a mask 16 and a control unit 18. The control unit 18 is connected to the mask 16 by a flexible pressure line 20 via a pressure port 22. The control unit 18 is also connected to a display 24 and to the blower 12 by respective cables 26 and 28. The blower 12 may be a CPAP flow generator such as the one marketed under the name Sullivan®V generator made by ResMed Ltd. of North Ryde, NSW, Australia.

The mask 16 is used to represent generically any suitable patient interface such as a nasal mask or a full face mask, such as the Mirage® mask made by ResMed, or other similar devices designed to deliver air from the generator 12.

The display 24 is designed to indicate graphically the operation of the apparatus 10 and the respiration of the patient, as indicated, for example, on chart 30. The display 24 may be a chart recorder, a CRT, a PC or a similar device.

Preferably, control unit 18 is programmable and includes a screen 32 and two rocker switches 34 and 36. The first rocker switch 34 is marked with up and down arrows, as shown, and is used to select a mode of operation from a menu on screen 32.

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The other switch 36 is marked with + and - symbols and may be used to select and change the values of certain programmable parameters associated with the operation of the apparatus 10. Finally, an override switch 38 is also provided on control unit 18 to override the operation of the apparatus. Control unit 18 monitors the operation of the blower 12 and generates a signal indicative of the respiration of the patient for display.

The apparatus 10 may be used to perform sleep studies and may be installed in a hospital, clinic, or patient's home. For this purpose, the control unit 18 monitors the respiration of the patient through mask 16 and configures the blower 12 to provide a controlled pressurized air into the mask 16 through conduit 14 when required, as is well known in the art.

As shown in Fig. 2, the control unit 18 includes a microprocessor 40, a pressure sensor 42, an analog-to-digital (A/D) converter 44, an amplifier 46 and a summer 48. The pressure sensor 42 is used to detect the current pressure within the mask 16 and to send a corresponding current pressure signal P_c to the A/D converter 44 and to the summer 48. The microprocessor 40 uses the current pressure P_c in the mask to derive a baseline pressure signal P_b which is summed with signal P_c .

More particularly, the summer 48 subtracts the baseline pressure signal P_b from the current pressure P_c . The resulting adjusted pressure P_a ($P_a = P_c - P_b$) is fed to the amplifier 46 which amplifies it at a gain G (selected by the microprocessor) to generate a respiration signal R .

Referring to Fig. 3, during operation of the apparatus the baseline pressure signal P_b is determined as follows. In step 100, a current pressure P_c is first determined dynamically by sensor 42. Using this signal P_c , and a nominal or default value P_{b0} (selected as discussed below), the signal P_a is calculated using formula $P_a = P_c - P_b$. This signal P_a is then amplified at gain G to obtain respiration signal R . In step 102 a long term average parameter P_l , which is indicative of a long term average of the respiration signal R , is calculated. Parameter P_l may be a moving average of the respiration signal taken over the previous 12 seconds.

In step 104, microprocessor 40 determines a short term average parameter P_s indicative of a short-term average of the respiration signal R . Parameter P_s may be a

moving average of the respiration signal taken over the previous 0.5 seconds. Parameter Ps is effectively indicative of the transient pressure noise within the mask.

These calculations are made by the control unit 18 to determine pressure variations within system 10 attributable to extraneous causes, *i.e.*, variations caused by factors other than the respiration of the patient. For example, if the blower 12 is a CPAP flow generator, then the pressure variations may be due to the generated CPAP (continuous positive airway pressure) air flow. The baseline pressure signal Pb is therefore set using these pressure variations, as discussed below.

Next, the microprocessor 40 performs three checks and adjusts the baseline signal Pb (if necessary) to compensate for extraneous air pressure variations. The first check (step 106) determines the deviation between the current baseline signal Pb and the CPAP. This check comprises taking the absolute difference between the long term parameter Pl and the current baseline pressure signal Pb, and comparing this absolute difference to a predetermined threshold pressure Pm. This threshold pressure Pm maybe a fraction (for example, 1/8th) of the output dynamic range of amplifier 46. If this absolute difference is larger than Pm, then in step 108 the baseline pressure Pb is set to the parameter Pl.

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If no significant deviation between the current signal Pb and CPAP is found in step 106, (*i.e.*, $|Pl - Pb| < Pm$) then a second check is performed in step 112. Under certain conditions, the CPAP can change rapidly. This rapid change may be due, for example, to an abrupt leak in the mask 16, or because the blower 12 is activated and starts pumping air into the mask. The purpose of this second check is to insure that the baseline signal Pb tracks the CPAP during its short-term excursion. More specifically, in step 112 a test is performed to determine whether the absolute difference between the short term average pressure parameter Ps and the baseline pressure signal Pb has exceeded a threshold pressure Pi for a period of Ti. The period Ti is defined as the maximum time period for which a healthy adult can sustain a continuous inspiration or expiration. Typically Ti is about 6 seconds and Pi is about 3 cm H₂O. Alternatively, the threshold pressure Pi may also be set as a fraction of the dynamic range of the amplifier.

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If in step 112 the absolute difference $|P_b - P_s|$ is determined to be greater than P_i for the last T_i seconds, then in step 114 the baseline pressure P_b is set to the parameter P_s . The process then recycles to step 100 with the new value for P_b being used instead of P_{b0} .

5 The third check is performed in step 116. This step is provided as a means for a clinician to override the current value of the baseline signal P_b . For example, when the clinician activates pushbutton 38 (Fig. 1), the microprocessor 40 receives an override control signal. If this override signal is sensed, then the baseline pressure signal P_b is set to P_s (step 118). The check for an override signal is shown step 116 as following a 'NO' decision in step 112, however, it may be performed at any other time.

10 When in automatic mode, the control unit operates in accordance with the flow chart of Fig. 3, as described above. However, certain parameters, such as the initial value of the baseline signal P_b and the gain G may be adjusted by the clinician. For example, baseline signal P_b may be set to a nominal or default level P_{b0} in the range of 0-35 cm H_2O using switch 36. If no manual override is detected in step 116 then the process recycles to step 100.

15 The effects of adjusting the baseline pressure signal P_b in the manner described in Fig. 3 are best understood by reference to the waveforms of Figs. 4A- E. In each of these figures, the current pressure (P_c) within the mask 16 is measured by pressure sensor 42 and processed by the circuit shown in Fig. 2. The respiration signal R of amplifier 46 is depicted as a function of time. Conventionally, a higher mask pressure (corresponding to exhalation) is shown as a negative signal (corresponding to a mask pressure) while inhalation is indicated in the Figures (when applicable) as a positive signal. When the respiration signal reaches the edge of the dynamic range of the amplifier it is clipped, as discussed in more detail below.

20 Fig. 4A shows the operation of the apparatus 10 when mask 16 is not secured to a patient and the baseline adjustment feature is disabled. As indicated in this figure, as signal R increases, it eventually reaches a maximum threshold M defined by the dynamic range of the amplifier 46. The respiration signal R is clipped at level M .

Fig. 4B is similar to Fig. 4A with the exception that the mask 16 has been secured to a patient and the respiration component is present. When signal R reaches level M, it is clipped.

Fig. 4C shows the respiration signal R and its long term average PI when the baseline adjustment feature has been activated. As this figure depicts, prior to $t=T1$, the long term average PI is relatively stable and baseline pressure signal Pb is set to its default value Pb0. At $t=T1$ the pressure signal increases rapidly, toward M, and stays at that level. Therefore both PI and Ps start increasing. As soon as PI exceeds Pb by more than the preselected threshold Pi, the baseline pressure is set to PI (steps 106, 108). But since PI increases relatively slowly and since Pa is very high, initially this change in Pb has no effect. After six seconds in this mode, however, the criteria of step 112 is met, and Pb is set to Ps (steps 112, 114). As a result, at $t=T2$ the respiration signal R is corrected automatically so that is centered around PI.

Fig. 4D shows the respiration signal R staying below the threshold level M but drifting slowly. Therefore, the long term average PI drifts as well. When PI becomes too large, Pb is adjusted as at T3 and T4 causing the respiration signal R to approach the horizontal axis. In this manner, the respiration signal R is maintained within the dynamic range of the amplifier 46.

Fig. 4E shows a sequence wherein initially at $t=T5$ there is a rapid change in the current pressure Pc. This change is handled by the system in the same manner as described above regarding Fig. 4C. This rapid change is corrected at $t=T6$ and is followed by a gradual pressure change. The gradual pressure change is corrected at $t=T7, T8, T9$ and $T10$ as shown.

Curves similar to those of Figs. 4A-4E can be shown on display 24 so that a patient's breathing and the operation of the baseline adjustment circuit of Fig. 2 can be monitored.

At any time, the clinician may activate the override pushbutton 38 which immediately sets the baseline pressure signal Pb to the short term average Ps, thereby rapidly centering the respiration signal R to the middle of the effective dynamic range of the system.

In summary, the subject device proffers the following advantages:

- a) It utilizes a DC-coupled amplifier, thereby insuring signal spectrum that extends to 0Hz.
- b) Its automatic baseline adjustment feature can be turned off at will, leaving
5 the clinician with the standard manual baseline adjustment.
- c) Changes in the respiration signal are presented clearly to the clinician. In one embodiment, automatic adjustments are indicated by explicit markers corresponding to changes in the baseline pressure signal.
- d) Adjustments of the baseline pressure signals are made only to prevent the
10 respiration signal from moving outside the dynamic range of the amplifier.
- e) Adjustments in the baseline pressure signal are preformed fast enough to track typical automatic or manual-titration without having the respiration signal R exceed the dynamic range of its amplifier.
- f) Tracking does not change as a result of respiratory activity because it
15 follows CPAP changes only.
- g) For very rapidly changing CPAP pressures (*e.g.*, during the start-up period of the blower) where automatic tracking may fail to keep up, a manual baseline capture is provided to allow instantaneous baseline adjustments .

The invention has been described in conjunction with a particular type respiratory
20 apparatus, however it may be incorporated into other kinds of devices as well. For example, in some respiratory devices respiration monitors are used which include effort sensors such as respiratory bands or suprasternal notch sensors. These effort sensors infer the effort expended by the patient during respiration and generate signals that are shown on a display. Under certain circumstances, for example when the patient moves
25 or shifts position, the sensor signals undergo a large shift which exceeds the dynamic range of the display. The present invention may be used in such devices to cause the sensor signals to return to the dynamic range of the display.

Obviously numerous modifications may be made to this invention without departing from its scope as defined in the appended claims.

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